

Applicant(s): Tarleton et al.

Serial No.: 09/518,156

Filed: March 2, 2000

For: PROPHYLACTIC AND THERAPEUTIC IMMUNIZATION AGAINST PROTOZOAN INFECTION AND DISEASE

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the claims presently under examination are drawn to a *method* for immunization, not an immunogenic *composition* (i.e., a protozoan vaccine as stated by the Examiner). Furthermore, the claimed method is not limited to stimulating a CD8<sup>+</sup> T cell response. An "immunogenic polypeptide" as recited in the claims includes a polypeptide that elicits an antibody-mediated immune response (i.e., a "B cell" response or humoral immunity), a cell-mediated immune response (i.e., a "T cell" response), or a combination thereof (page 19, lines 26-29, of the specification).

#### **Restriction/Election**

Applicants' election of Group IV (claims 40-69), with traverse, has been acknowledged by the Examiner. Applicants' species elections include (e) *Trypanosoma* as the protozoan species; (f) a polynucleotide as the vaccine component species; and (g) therapeutic administration as the vaccine administration species.

Applicants indicated in the response mailed July 27, 2001, and received by the USPTO on July 30, 2001, that claims 40-44, 46-50, 52, 53, 65-67 and 69 read on the elected species. However, the Examiner did not include claims 52 and 53 in the set of examined claims.

Applicants maintain that the exclusion of claims 52 and 53 from examination was in error because these claims are directed to, *inter alia*, therapeutic administration (species (g)) of a vaccine comprising a polynucleotide (species (f)) to treat a *Trypanosoma* infection (species (e)). Accordingly, examination of claims 52 and 53 as drawn to the elected species within Group IV is respectfully requested.

#### **Rejection under 35 U.S.C. §103(a)**

The Examiner rejected claims 40-44, 46-50, 65-67, and 69 under 35 U.S.C. §103(a) as being unpatentable over Lambert et al. (U.S. Patent. No. 5,646,114) in view of Denkers et al. (Clin. Microbiol. Rev., 11(4):569-588 (Oct. 1998)). This rejection is respectfully traversed.

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The claims under examination as a result of the Applicants' restriction and species election encompass therapeutic immunization of a mammal harboring a persistent *Trypanosoma* infection. The method under examination includes administering to the infected mammal a multicomponent vaccine containing a polynucleotide having a nucleotide coding region encoding an immunogenic polypeptide, wherein administration of the vaccine is effective to eliminate the parasite from the mammal (claims 40-44) or to prevent or delay chronic debilitating disease in the mammal (claims 46-50, 65-67, and 69). The immunogenic polypeptide is derived from a protozoan (claim 1).

In rejecting the claims, the Examiner cites Lambert et al. as teaching a method of therapeutic immunization of a mammal harboring *Trypanosoma cruzi* infection which comprises administering a vaccine (page 4 of the Office Action). However, as noted above, the presently claimed method involves administration of an immunogenic polypeptide *derived from a protozoan*. Lambert et al. teach administration of an entirely different compound: a *mammalian* (i.e., host-origin) bacteriocidal/permeability increasing (BPI) protein (col. 4, lines 13-14). The similarities between the teachings of Lambert et al. and the present invention begin and end with the statement of the problem: treatment of *T. cruzi* infection. It is respectfully submitted that the claimed method for treating *T. cruzi* infection (administration of an immunogenic compound derived from a pathogenic protozoan) is patentably distinct from the solution proposed by Lambert et al. (administration of a host-origin bacteriocidal compound).

A CD8<sup>+</sup> T cell response in the host is not taught in Lambert et al., and the Examiner cites the secondary reference, Denkers et al., for this teaching. Applicants note that stimulation of a CD8<sup>+</sup> T cell response is recited in only two claims (claims 43 and 49), and not in the other claims under examination. Furthermore, Denkers et al. teach only that *infection* by *T. cruzi* may lead to a CD8<sup>+</sup> T-cell response; they do not teach a *vaccine* that successfully stimulates the host's CD8<sup>+</sup> T cell response. Specifically, Denkers et al. teach that "infection with *Trypanosoma cruzi* . . . results in the presentation of parasite-derived peptide with cell surface

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MHC class I glycoproteins, in turn inducing CD8<sup>+</sup> CTL [cytotoxic T lymphocyte] effector function" (page 578, left column, second paragraph under the heading Cytolytic T-Cell Activity).

It is therefore respectfully submitted that the cited document(s), alone or in combination, neither teach nor suggest all of the limitations of the rejected claims. In particular, the cited documents neither teach nor suggest, nor do they successfully demonstrate as do the Applicants, administration of an *immunogenic compound derived from a protozoan* to treat or prevent a protozoan infection. Accordingly, reconsideration and withdrawal of the rejection of claims 40-44, 46-50, 65-67, and 69 under 35 U.S.C. §103(a) is respectfully requested.

#### **Information Disclosure Statement**

1. Information Disclosure Statement mailed September 29, 2000, and received by the U.S. Patent and Trademark Office on October 4, 2000.

In a telephone conference with Applicants' Representative Brian Walsh on October 24, 2001, the Examiner stated that the documents associated with the Information Disclosure Statement mailed September 29, 2000, had been located, and indicated that it was not necessary to provide replacement copies of the documents. In reliance on this statement, copies of the 133 documents referred to in the Information Disclosure Statement and listed on the PTO 1449 forms are not included with this Response. For the Examiner's convenience, copies of the Information Disclosure Statement and pages 1-12 of the PTO 1449 forms are attached hereto as Exhibit A. A copy of the return postcard with the PTO date stamp is also attached hereto as Exhibit B. Pursuant to the provisions of M.P.E.P. §609, Applicants request that a copy of the PTO 1449 forms that accompanied the Information Disclosure Statement filed September 29, 2000, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

In the event the documents were not located, it is respectfully requested that the Examiner provide an opportunity for submission of the documents for consideration prior to the issuance of the next Office Communication on the merits.

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2. Supplemental Information Disclosure Statement mailed October 27, 2000, and received by the U.S. Patent and Trademark Office on October 30, 2000.

A Supplemental Information Disclosure Statement was mailed on October 27, 2000, and received by to the U.S. Patent and Trademark Office on October 30, 2000, but the initialed PTO 1449 form has not been returned to the Applicants. For the Examiner's convenience, copies of the Supplemental Information Disclosure Statement and page 1 of the PTO 1449 form are attached hereto as Exhibit C. A copy of the return postcard with the PTO date stamp is also attached hereto as Exhibit D. Pursuant to the provisions of M.P.E.P. §609, Applicants request that a copy of the PTO 1449 form that accompanied the Supplemental Information Disclosure Statement filed October 27, 2000, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

#### **Request for Rejoinder**

Claims 45, 51-64 and 68, although included in the invention of Group IV elected by Applicants, stand withdrawn from examination as a result of Applicants' species election.

For reasons set forth above, it is respectfully submitted that the claims presently under examination (claims 40-44, 46-50, 65-67, and 69) are in condition for allowance. In addition, as noted above, it is submitted that claims 52 and 53, which Applicants submit are also in condition for allowance, were erroneously excluded from examination and should therefore be rejoined.

It is further submitted that claims 40, 43, 46, 49, 52, 53, 65 and 67 are generic, and that withdrawn claims 45, 51, 54-64 and 68, by virtue of their dependence on allowable generic claims, should be rejoined pursuant to 37 C.F.R. §1.141 and found allowable as well.

Rejoinder of claims 45, 51-64 and 68 is, accordingly, respectfully requested.

**Response Under 37 C.F.R. §1.111**

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**Summary**

It is respectfully submitted that claims 40-44, 46-50, 65-67, and 69 presently under examination are in condition for allowance. Rejoinder of claims 45, 51-64 and 68 is requested, and notification of the allowance of claims 40-69 (the invention of Group IV) is earnestly requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be in any way assisted thereby.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 12<sup>th</sup> day of November, 2001.

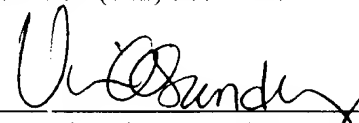
  
Victoria A. Sandberg

Respectfully submitted,

Tarleton et al.

By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Telephone: (612) 305-1220  
Facsimile: (612) 305-1228

November 12, 2001  
Date

By:   
Victoria A. Sandberg  
Reg. No. 41,287  
Direct Dial (612) 305-1226